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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,550	01/26/2001	Komei Washino	Q62780	9592

7590 09/09/2004

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EXAMINER	
MITCHELL, GREGORY W	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/744,550	WASHINO ET AL.	
	Examiner	Art Unit	
	Gregory W Mitchell	1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuing Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuing Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *36-43*.

   Claim(s) withdrawn from consideration: *22-34*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____

10. ☐ Other: _____

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

3. Examiner has found Applicant's arguments regarding the 112(1) written description rejection of claims 36-39 and 41-43 persuasive and the rejection is hereby withdrawn.

5. Examiner has considered Applicant's arguments regarding the remaining 112(2) and 102(b) rejections and has found them unpersuasive for the reasons of record in the previous office action and for the following reasons:

112(2) rejection of claims 36-39 and 41-43: Applicant's arguments that the phrase: "concentration of the active ingredient equal to a concentration of the active ingredient in the administrative form of the medicament," is not indefinite is not persuasive. The Merriam-Webster Third New International Dictionary (1961, p. 1402) defines a medicament as "a substance (as a chemical, a medicine, or an ointment) used in therapy." Accordingly, a medicament is, by definition, in administrative form. Therefore, the afore mentioned phrase is indefinite because the concentration of the active agent in the medicament is being defined as the concentration of that active agent in the medicament. It is understood by Examiner, by reading Applicant's response, that this phrase is not intended to be redundant but it is so, by definition.

102(b) rejection of claims 36-39:

Applicant argues that "the active ingredient in the composition of Yu et al. was determined for the purpose of an in vitro NMR analysis ... and is not equal to a concentration of the active ingredient in the administrative form of a medicament." Examiner maintains the argument of the previous action: that 1) the object of the invention is irrelevant as the invention is drawn to a composition and 2) that the concentrations have not been shown to be fundamentally different. Applicant addresses 2) by stating "the concentrations that are employed are concentrations that are used to obtain medical benefits." Again, for reasons addressed in the previous office action, this is not persuasive - this does not provide evidence that the concentrations are fundamentally different. Applicant also argues that "the administrative form of FK506 ... is (a) capsules for oral administration comprising 0.5 to 5 mg anhydrous tacrolimus and inactive ingredients ... or (b) injections containing the equivalent of 5 mg anhydrous tacrolimus in 1 mL for administration by intravenous infusion ..." Applicant continues by addressing RapamuneTM: "The form is for an oral administration selected from (a) an oral solution containing 1 mg/mL sirolimus, or (b) tablets containing 1-mg or 2-mg sirolimus." It is Examiner's position that these do not overcome the instant rejection because, while both address a concentration in one of the dosage forms, each has another dosage form which simply recites a mass of the agent to be administered. Accordingly, the concentration is not defined by this information and Examiner maintains the rejection over this argument because the composition taught by Yu et al. could be administered in a volume whereby appropriate dosage is administered.

Applicant also argues that "the drug composition of the present application recited in claims 36 to 39 is an administrative form containing the constituent matters of a composition equal to the medicament to be used for the therapeutic treatment in an equal administrative form to said medicament" and that the composition of Yu et al. is not in administrative form and does not, therefore, anticipate claims 36-39. This argument is not persuasive because it is Examiner's position that the claims do not possess this limitation. The only limitation regarding the administrative form of the medicament is regarding the concentration: "a concentration of the active ingredient in the resulting drug composition is equal to a concentration of the active ingredient in the administrative form of the medicament." Concentrations of the medicament can be identical without the form of the medicament being identical.